

REMARKS

Upon entry of the foregoing amendments, claims 18, 25, 27, 28, 30 and 32-34 are currently pending in the present application. Claim 18 is amended. The amendment made with the expectation that it will place this application in condition for. Support for this amendment can be found at paragraph 15 of the instant application. Therefore, the amendment does not introduce new matter within the meaning of 35 U.S.C. §132. Accordingly, entry of the amendment is respectfully requested.

In view of the following, further and favorable consideration is respectfully requested.

1. Claim Rejection - 35 U.S.C. §103(a)

In the Official Action, claims 18, 25, 27, and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trogolo et al. (U.S. Patent No. 5,762,638) in view of Pourrezai et al. (U.S. Patent No. 5,685,961).

Applicant respectfully traverses this rejection.

The Examiner has failed to establish a *prima facie* case of obviousness against the rejected claims. To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court very recently held in *KSR International Co. v. Teleflex Inc. et al.*, Slip Opinion No. 04-1350, 550 U. S. __ (April 30, 2007), “a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” (*KSR, supra*, slip opinion at 13-15.) Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Presently Claimed Subject Matter

The presently claimed subject matter as amended in claim 18 of the subject application, relates to a vascular prosthesis having a particular laminate-type structure as follows:

A vascular prosthesis for replacement of hollow organs with antibiotic long-term action with a basic structure which defines the form of the prosthesis and which is made of substantially non-absorbable or only slowly absorbable polymer material and of a coating of an absorbable material, with a layer of metallic silver situated on the polymer material and underneath the coating,

wherein the silver layer is a substantially closed layer having thickness of 2500 to 1000 Å, breaks down in the body at a maximum of 5 to 10% per annum, adheres firmly on the polymer material by vapor-deposition, and wherein silver atoms of the silver layer are impressed into the polymer surface of the basic structure and the silver layer is a closed layer; and

the basic structure is porous made from a textile material, the silver layer leaves the pores open and the absorbable coating layer is an impregnation which seals the pores of the prosthesis and is chosen such that it is absorbed at the latest after four months.

Again, the Examiner's attention is directed to the **metallic** silver layer covered by an absorbable polymer coating. Thus, the silver layer is **on** the polymer material and **underneath** the absorbable coating, and therefore it provides an improved releasing rate of silver.

The essential feature of the instant claims in that as a long-time active antibiotic interposed between a base structure polymer material and an absorbable polymer material coating, a layer of metallic silver is provided. The silver layer is prepared by vapor-deposition method to coat uncharged elemental silver on the polymer surface.

Furthermore, the silver of the instantly claimed implant is present as a homogenous and uniform layer having a thickness of 1000 to 2500 Å and is comprised of about 80 to 100 atomic layers. Due to the surface deposition method employed using argon impact, silver atoms are to a certain extent pushed or impressed into the polymer surface. Thus, the silver atoms are anchored or fixed to the polymer material. The silver layer is a closed layer to cover the polymer material of the base structure, which has been amended into the claims for clarification. The silver layer is then covered by an absorbable top coating.

Trogolo et al.

Trogolo et al., contrary to the Examiner's assertion, does not teach a layer of metallic silver or elemental silver. Specifically, Trogolo et al. teach an inorganic agent of **metal ions** which can include silver. Further disclosed are zeolites, at col. 4, line 12, et seq. Applicant submits for the Examiner's easy reference a print out from the Encyclopedia Britannica defining "zeolite" and the interaction of zeolites with metal ions. Even further disclosed in Trogolo et al., at col. 6, lines 5, et seq., are the use of ion exchangeable metals. Finally, at col. 6, lines 16-18, the Trogolo et al. disclosure states, "other inorganic antimicrobial agents, i.e., those containing silver..." Thus, it becomes clear that the disclosure of Trogolo et al. does not at all teach metallic silver, but only contemplates silver as an ion or zeolite or potentially in combination with something else. Thus, it is clear the one of skill in the art would not, contrary to the Examiner's assertion otherwise, read that Trogolo et al. teaches a layer of metallic or elemental silver.

Furthermore, Applicant respectfully submits that Trogolo et al. discloses a different structure than that of the instantly claimed subject matter. Namely, the antimicrobial agent of Trogolo et al. is bonded to the coating material. See, col. 3, lines 43-65. In contrast, the antibiotic of the instant claims **adheres** to a polymer base structure and is covered by an absorbable coating.

Pourrezai et al.

The Examiner states the Pourrezai et al. teaches the decomposition rate of silver. On this basis, the Examiner extrapolates that the thickness of the silver layer may be calculated according to how long a patient will require an implant and that it would have been obvious to one of ordinary skill in the art to make a silver layer thick enough to last for the necessary time. Applicant respectfully submits that what is taught in Pourrezai et al. is an **expected or predicted** decomposition rate for silver. See, col. 7, lines 33-39. Furthermore, the metal coatings applied by Pourrezai et al. are not covered or protected by bioabsorbable coating and are therefore

exposed directly to a physiological environment. Thus, contrary to the Examiner's assertions, a person of skill in the art would not view the teachings of Pourrezai et al. as providing a simple rate to be inserted into a formula to arrive at the instantly claimed decomposition rate. On the contrary, one of ordinary skill in the art would view the claimed subject matter as extending well beyond the teachings of Pourrezai et al. since the claimed silver layer is not exposed directly to the physiological environment, but instead covered by an additional coating which would alter the rate of the silver decomposition and thereby render the teachings of Pourrezai et al. incomplete in this regard.

As such, Applicant submits that the combination of Trogolo et al. and Pourrezai et al. fail to teach or suggest all the elements of the presently claimed vascular prosthesis, and thereby fail to render the presently claimed vascular prosthesis obvious.

2. Claim Rejection - 35 U.S.C. §103(a)

In the Official Action, claims 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trogolo et al. (U.S. Patent No. 5,762,638) in view of Pourrezai et al. (U.S. Patent No. 5,685,961) in further view of Shikani et al. (U.S. Patent No. 5,762,638).

Applicant respectfully traverses this rejection.

The instant subject matter, as well as Trogolo et al. and Pourrezai et al., are discussed above.

Shikani et al.

Shikani et al. teach that active agents can be included in the absorbable coating. See, col. 5, lines 47-62. There various active agents are shown "loaded in" a polymer coating, which will release the active upon contact with a biological fluid. Applicant respectfully submits that this is not the instantly claimed subject matter. The instantly claimed subject matter is, *inter alia*,

requires in the following order: a base polymer, silver atoms and an absorbable coating. The atoms of silver, according to the instantly claimed subject matter are anchored to the base polymer and are not (as is the case with Shikani et al.) interposed within an overlying coating.

Shikani et al. do not remedy the deficiencies of Trogolo et al. discussed above.

Shikani et al. disclose invasive medical devices in which a polymer has been coated or incorporated with anti-infective and/or anti-inflammatory agents and in which the polymer comprises pharmaceutical compositions that have a delayed or sustained release from said polymer. Shikani et al. do not disclose a metallic silver layer in combination with an absorbable material with the particular laminate-type structure in the presently claimed vascular prosthesis, let alone the vapor-deposition method and the thickness of the silver layer.

Accordingly, the combination of Trogolo et al., Pourrezai et al., and Shikani et al., do not render the instantly claimed subject matter obvious.

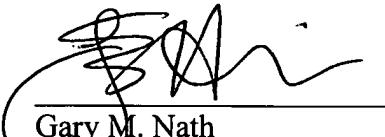
CONCLUSION

Based upon the above remarks, the presently claimed subject matter is believed to be patentably distinguishable over the prior art of record. The Examiner is respectfully requested to reconsider and withdraw the outstanding rejections and allow all pending claims 18, 25, 27, 28, 30 and 32-34. Favorable action with an early allowance of the claims pending in this application is earnestly solicited.

The Examiner is invited to contact the undersigned attorney if it is believed such contact will expedite the prosecution of the application. Also, if the Examiner has any questions or comments regarding this matter, he is welcomed to contact the undersigned attorney at the below-listed number and address.

Respectfully submitted,

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Attachment A

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any member of a family of hydrated aluminosilicate minerals that contain alkali and alkaline-earth metals. The zeolites are noted for their lability toward ion-exchange and reversible dehydration. They have a framework structure that encloses interconnected cavities occupied by large metal cations (positively charged ions) and water molecules.

> zeolite facies

one of the major divisions of the mineral facies classification of metamorphic rocks, the rocks of which formed at the lowest temperatures and pressures associated with regional metamorphism. It represents the transition between the sedimentary processes of diagenesis and the distinct regional metamorphism exhibited by the greenschist facies. This facies was first ...

> Zeolite facies*from the metamorphic rock article*

In the zeolite facies, sediments and volcanic debris show the first major response to burial. Reactions are often not complete, and typical metamorphic fabrics may be poorly developed or not developed at all. This is the facies of burial metamorphism.

> thomsonite

rare mineral in the zeolite family, similar to natrolite (q.v.).

> stilbite

mineral similar to heulandite (q.v.), a member of the zeolite family.

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In some areas extra soap is needed for washing objects such as clothing because the water is hard. Hard water contains certain dissolved minerals, such as calcium bicarbonate, magnesium bicarbonate, and calcium sulfate, which make it difficult for soap to lather.

Silicate Minerals*from the mineral article*

The most widespread and numerous minerals are the silicates. They consist of silicon and oxygen combined with potassium, sodium, magnesium, aluminum, and many other elements.

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